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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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07/953, 060 11/05/92 ALIZON

M 3495.0010-07

RAILEY, EXAMINER

18M2/0517

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1804

11

DATE MAILED: 05/17/94

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

This application has been examined  Responsive to communication filed on 24 NOV, 15 FEB 1994 A  This action is made final.

A shortened statutory period for response to this action is set to expire \_\_\_\_\_ month(s), \_\_\_\_\_ days from the date of this letter.  
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1.  Notice of References Cited by Examiner, PTO-892.
2.  Notice of Draftsman's Patent Drawing Review, PTO-948.
3.  Notice of Art Cited by Applicant, PTO-1449.
4.  Notice of Informal Patent Application, PTO-152.
5.  Information on How to Effect Drawing Changes, PTO-1474.
6.  \_\_\_\_\_

Part II SUMMARY OF ACTION

1.  Claims 13 <sup>i5</sup> pending in the application.

Of the above, claims \_\_\_\_\_ are withdrawn from consideration.

2.  Claims \_\_\_\_\_ have been cancelled.

3.  Claims \_\_\_\_\_ are allowed.

4.  Claims 13 <sup>i5</sup> rejected.

5.  Claims \_\_\_\_\_ are objected to.

6.  Claims \_\_\_\_\_ are subject to restriction or election requirement.

7.  This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.

8.  Formal drawings are required in response to this Office action.

9.  The corrected or substitute drawings have been received on \_\_\_\_\_. Under 37 C.F.R. 1.84 these drawings are  acceptable;  not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).

10.  The proposed additional or substitute sheet(s) of drawings, filed on \_\_\_\_\_, has (have) been  approved by the examiner;  disapproved by the examiner (see explanation).

11.  The proposed drawing correction, filed \_\_\_\_\_, has been  approved;  disapproved (see explanation).

12.  Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has  been received  not been received <sup>UK 84 29099</sup>  
<sup>13</sup> been filed in parent application, serial no. 08/156,930; filed on \_\_\_\_\_.

13.  Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

14.  Other

EXAMINER'S ACTION

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claim 11, drawn to nucleic acid having various HIV-1 sequences, classified in Class 536, subclass 24.1.

II. Claim 12, drawn to peptides encoded by HIV-1, classified in Class 530, subclass 350+.

The inventions are distinct, each from the other because of the following reasons:

Inventions of Group I and Group II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (M.P.E.P. § 806.05(f)). In the instant case HIV proteins may either be synthesized chemically or derived from a natural source, such as the virus.

Also, the nucleic acids of group I have a separate and distinct utility as probes and not necessarily for the expression of the proteins of Group II.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and subject matter, as well as their being

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separately and independently searched, restriction for examination purposes as indicated is proper.

During a telephone conversation with Kenneth J. Meyers on 30 March 1993 a provisional election was made with traverse to prosecute the invention of Group I, claim 11. Affirmation of this election must be made by applicant in responding to this Office action. Claim 12 is withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

35 U.S.C. § 101 reads as follows:

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title".

Claim 11 is rejected under 35 U.S.C. § 101 because the invention as claimed lacks patentable utility and as disclosed is inoperative.

Applicant claims nucleotide sequences from HIV-1. In particular, applicant cites for support the specification page 3, line 35 through

page 4, line 3; page 7, lines 18-26; page 12, line 29 through page 13, line 18; and page 15, lines 18-21. These citations do set forth what is being claimed, but does not demonstrate a utility for these nucleotide sequences. On page 14, lines 11-19 the disclosure holds that DNA can be used for "cloned probes". In addition, page 15, lines 18-24, notes of "polypeptides themselves which can be expressed by the different DNAs of the instant inventions, particularly by the ORFs or fragments thereof."

Applicant has not demonstrated a utility for these sequences as probes. How specific are they for detecting HIV and distinguishing it from other retroviruses, in particular HTLV I and II? Applicant has not demonstrated that these sequences function to have the utility as described.

Also, applicant notes in the specification, in particular Figures 2 and 3, that the nucleic acids claimed are "ORFs." Applicant believes that the nucleic acid sequences claimed are translatable into proteins having distinct sequences, such protein thereby having various utilities as stated in the specification. However, applicant has not demonstrated that these nucleic acid sequences comprising these "ORFs" are indeed translated into proteins having a demonstrable utility. Therefore, the nucleic acids as claimed have no demonstrated utility.

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Claim 11 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11 is directed to nucleotide sequences. Applicant should be claiming nucleic acid having the particular sequence shown. As written, the claims are drawn simply to the printed sequence which represents the nucleic acid, rather than to the nucleic acid itself.

The preliminary amendment filed 29 September 1992, paper No. 5, contains contradictory and duplicative information regarding the "Cross-Reference to Related Application" to that filed with the request for filing of a Divisional application under 37 CFR 1.60, paper No. 4, also filed 29 September 1992. Paper No. 5 correctly states that the instant application is a "division" of application Serial No. 07/158,652. However, Serial No. 07/158,652 is not a continuation of application Serial No. 07/647,214, but rather is a divisional of application Serial No. 06/771,248. The information in Paper No. 4 appears to be the correct of the two. Also, essentially all of this material is duplicative when inserted on page 1, before the first line of the specification. Correction is requested.

Papers related to this application may be submitted to Group 180 by facsimile transmission. Papers should be faxed to Group 180 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 305-3014.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. F. Railey whose telephone number is (703) 308-0281.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Johnny F. Railey II  
May 25, 1993

*JStone*  
JACQUELINE STONE  
PRIMARY EXAMINER  
ART UNIT 1804